

REMARKS

Applicants have made the foregoing amendments to place the PCT application text in customary US format, so that all the claims can be considered on their merits. All multiple dependent claims have been cancelled.

The specification has been amended to insert customary headings and to replace references to the content of the claims. Most of the foreign documents (or their English equivalents) mentioned in the specification are included in the Information Disclosure Statement filed herewith. If the Patent Office notes any remaining informalities which would prevent or hinder examination on the merits, a telephone call to Applicants' counsel is requested.

Respectfully submitted,

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CLAIMS TEXT MARKED TO SHOW CHANGES MADE

1. (Amended) An injection device comprising
a container (80) for reception of a cartridge (52) which
contains an injection fluid (53) and on whose proximal end an
injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said
container (80) is displaceable between a proximal end position
and a distal end position,

[comprising] a plunger (108), arranged in the barrel and
serving to expel injection fluid (53) out of the cartridge (52),
which plunger during an injection is guided in a guide member
(124) axially displaceably but nonrotatably relative to the
barrel, and which has an external thread (159) that is guided in
an internal thread (152) of a setting member (151) serving to set
the injection dose,

and [comprising] a frictionally engaging coupling (162,
250), in the manner of a slip coupling, between the container
(80) and the plunger (108), for transferring at least a portion
of an axial movement of the plunger (108) to the container (80).

2. (Amended) The injection device according to claim 1, [in
which] wherein the setting member (151) has associated with it a
spring (172) for biasing the setting member (151) in the proximal
direction, and the setting member (151) [can be displaced]
is displaceable against the force of said spring (172) into a
distal position (FIG. 3) and [releasably latched] is releasably
latchable there.

3.(Amended) The injection device according to claim 2, wherein

the setting member (151) [can be displaced] is displaceable from the proximal end of the barrel into a distal position (FIG. 3) and [releasably latched] is releasably latchable there.

4.(Retyped) The injection device according to claim 3, wherein

for cocking the spring (172), a cocking member (56) is provided which can be joined, from the proximal end of the injection device (30), to a thread (60) of the injection device, in order to displace the container (80), using a distal end region of the cocking member (56), in the proximal direction.

5.(Amended) The injection device according to claim 1, [one or more of the foregoing claims,] wherein

the setting member (151) is, in at least one distal position (FIG. 2), rotatable relative to the barrel of the injection device in order to make possible an axial displacement of the plunger (108) relative to the barrel for the purpose of setting an injection dose (Y).

6. (Amended) An injection device comprising
a container (80) for reception of a cartridge (52) which
contains an injection fluid (53) and on whose proximal end an
injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said
container (80) is displaceable between a proximal end position
and a distal end position,

[comprising] a plunger (108), arranged in the barrel and
serving to expel injection fluid out of the cartridge (52), which
is guided in a guide member (124) axially displaceably but
nonrotatably relative to the guide member, and which has an
external thread (159) that is guided in an internal thread (152)
of a setting member (151),

[comprising] a cocking spring (172) biasing the setting
member (151) in the proximal direction and, during an injection
operation, causes displacement thereof into a proximal end
position, and against the force of which the setting member (151)
can be displaced into a distal end position and releasably
latched there,

[comprising] a first coupling arrangement (K4), for
nonrotatable but axially displaceable coupling of the setting
member (151) to the barrel, which is deactivated in the distal
end position of the setting member (151),

and [comprising] a second coupling arrangement (K5), for
nonrotatable but axially displaceable coupling of the guide
member (124) to the barrel, which is activated in the entire
region between the distal and proximal end positions of the guide
member (124).

7. (Retyped) The injection device according to claim 6,
comprising

a connection (282), provided between guide member (124) and

setting member (151), that joins said parts to one another rotatably but substantially axially nondisplaceably.

8. (Amended) The injection device according to claim 6₁ [or 7,] wherein

both the guide member (124) and the setting member (151) have external splines (274 and 222, respectively), and said external spline sets have associated therewith internal splines (134) in the barrel (36), into which said external spline sets (222, 274) can engage, individually or together, by means of a longitudinal displacement of guide member (124) and setting member (151) occurring relative to the barrel (36).

9. (Retyped) The injection device according to claim 8, wherein

the setting member (151) is equipped with a latching member (64), by means of which the setting member (151) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (222) are not in engagement with the internal splines (134) in the barrel (36).

10. (Amended) The injection device according to claim 8 [or 9], wherein the setting member is equipped with a latching member (64), by means of which the guide member (124) can be releasably latched in a predefined axial position relative to the barrel (36) in which its external splines (274) are in engagement with the internal splines (134) in the barrel (36).

11. (Amended) The injection device according to claim 9₁ [or 10,] wherein the setting member (151) is rotatable relative

to the latching member (64) provided on it.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 12-35.

36. (Amended) An injection device comprising
a barrel (50, 48, 46, 36),

[comprising] a plunger (108), arranged in said barrel and
serving to expel injection fluid out of a container (52)
containing an injection fluid,

which plunger is guided in a guide member (124) axially
displaceably but nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an
internal thread (152) of a setting member (151),

[comprising] a cocking spring (172) which biases the setting
member (151) in the proximal direction,

[comprising] a latch (38, 64), provided between barrel and
setting member (151), for releasably latching the setting member
(124) in a distal position (FIG. 23) in which the cocking spring
(172) is cocked,

the cocking spring (172), after disengagement of the latch
(38, 64), displacing the setting member (151) a defined distance
(FIG. 25: L) out of said distal position (FIG. 23) into a
proximal end position (FIG. 25),

[comprising] external splines (222), provided on the setting
member (151), for longitudinal guidance of the setting member
(151) in barrel-mounted internal splines (134) substantially
complementary to said splines (222),

and [comprising] external splines (274), provided on the
guide member (124), for longitudinal guidance of the guide member
(124) in the barrel-mounted internal splines (134).

37. The injection device according to claim 36, wherein
the length of the barrel-mounted internal splines (134)

corresponds at least to the aforesaid predefined distance (L).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 38-43.

44. (Amended) An injection device comprising
a container (80) for reception of a cartridge (52) which
contains an injection fluid (53) and on whose proximal end an
injection needle (76) can be mounted,

[comprising] a barrel (50, 48, 46, 36) in which said
container (80) is displaceable between a proximal end position
and a distal position,

[comprising] a plunger (108), arranged in the barrel and
serving to expel injection fluid (53) out of the cartridge (52),
which plunger during an injection is guided in a guide member
(124) axially displaceably but nonrotatably relative to the
barrel, and which has an external thread (159) that is guided in
an internal thread (152) of a setting member (151) serving to set
the injection dose,

and [comprising] an apparatus for modifying an axial spacing
(Y) in the region between the setting member (151) and the
container (80) for purposes of dose setting.

45. (Amended) The injection device according to claim 44,
wherein during an injection, the axial spacing (Y) increased upon
dose setting is [reduced, and in particular is] reduced to zero.

46. (Amended) An injection device comprising
a container (80) for reception of a cartridge (52) which
contains an injection fluid (53) and on whose proximal end an
injection needle (76) can be mounted,

[comprising] a plunger (108), arranged in the barrel and
serving to expel injection fluid (53) out of the cartridge (52),
which plunger has an external thread (159) that is guided in an

internal thread (152) of a setting member (151) serving to set the injection dose,

and which is guided axially displaceably in a guide member (124),

[comprising] a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, the torque transferable from the container (80) to the guide member (124).

47. The injection device according to claim 46, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 48-50.

51. (Amended) An injection device comprising a barrel (36, 46, 48) wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated therewith a setting member (32) for dose setting,

and the dose-setting apparatus being, at least in its proximal end position (FIG. 25), out of engagement with said setting member (32).

52. (Amended) An injection device [, in particular] according to claim 51, wherein a dose-setting apparatus (FIG. 15), for setting a fluid quantity to be injected, is arranged displaceably between a distal end position (FIG. 3) and a proximal end position (FIG. 25),

said dose-setting apparatus having associated with it a

setting member (32) for dose setting,

and the dose-setting apparatus (FIG. 15) being, at least in its distal end position (FIG. 3), out of engagement with said setting member (32).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 53-67.

68. (Amended) An injection device comprising
an indicating apparatus for the injection dose that is set,
[in particular according to one or more of the foregoing claims,]
in a generally cylindrical automatic injection device,
comprising a scale (69') [which comprises] having,
in a first row (71), a first series of indicating digits and,
in a second row (73), a second series of indicating digits,
and [comprising] a double magnifier (42), serving to
indicate the dose, of which [the one magnifier] a first lens (70)
is associated with the first row (71), and [the other magnifier]
a second lens (72) is associated with the second row (73), of
indicating digits.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 69-70.

71. (Amended) An injection device comprising
a housing (50, 48, 46, 36) with a container (80), arranged
in said housing, for reception of a cartridge (52) which contains
an injection fluid (53) and on whose proximal end an injection
needle (76) can be mounted,

[comprising] a plunger (108), arranged in the housing and
serving to expel injection fluid out of the cartridge (52), which
is guided in a guide member (124) axially displaceably but
nonrotatably relative to the guide member,

and which has an external thread (159) that is guided in an
internal thread (152) of a setting member (151) provided for dose

setting,

[comprising] a first coupling arrangement (K4) for nonrotatable but axially displaceable coupling of the setting member (151) to the housing, said coupling arrangement (K4) being deactivated during dose setting,

[comprising] a second coupling arrangement (K5) for nonrotatable but axially displaceable coupling of the guide member (124) to the housing,

and [comprising] an apparatus (50) for activating the first coupling arrangement (K4) and for disabling the second coupling arrangement (K5), in order to make the guide member (124) rotatable relative to the housing and the setting member (151) nonrotatable relative to the housing, and to make possible an axial movement of the plunger (108) by rotation of the guide member (124).

72. (Amended) The injection device according to claim 71, wherein there is provided, between guide member (124) and setting member (151), a connection (278, 282) that joins said two parts to one another rotatably but substantially axially nondisplaceably.

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 73-104.

105. (Amended) An injection device comprising a container (80) for reception of a cartridge (52) which contains an injection fluid (53) [and on whose] said cartridge having a proximal end adapted for mounting thereon of an injection needle (76) [can be mounted],

[comprising] a housing (50, 48, 46, 36) in which said container (80) is displaceable between a proximal and a distal position,

[comprising] a plunger (108), arranged in the housing and

serving to expel injection fluid (53) out of the cartridge (52), which has an external thread (159),

[that is guided in an internal thread (152) of]

a setting member (151) having an internal thread (152) adapted to engage said external thread (159 of said plunger, said setting member serving to set the injection dose,

and [which is] said setting member being guided axially displaceably in a guide member (124), and [comprising]

a drive connection (232, 234, 266, 268, 270, 272) which is provided between the guide member (124) and the container (80) and which comprises an apparatus (118, 242; 232, 234) that limits, in at least one rotation direction, a torque transferable from the container (80) to the guide member (124),

in order to make possible, by the transfer of a limited torque from the container (80) to the guide member (124) after a cartridge replacement, a displacement of the plunger (108) in the proximal direction into contact against a piston (106) provided in the cartridge (52).

106. (Retyped) The injection device according to claim 105, wherein the apparatus for limiting the torque comprises a slip coupling (232, 234).

PLEASE CANCEL, WITHOUT PREJUDICE, CLAIMS 107-108.

VERSION MARKED TO
INJECTION DEVICE SHOW CHANGES

FIELD OF THE INVENTION

The invention concerns an injection device comprising a container for reception of a cartridge which contains an injection fluid and on whose proximal end an injection needle can be mounted.

BACKGROUND

An injection device of this kind is known from DE 42 23 958 A1. and USP. . . .
The injection device depicted and described therein operates very reliably and precisely, but is less suitable for the use of large cartridges comprising larger quantities of injection fluid.

SUMMARY OF THE INVENTION

It is therefore an object of the invention to make a new injection device available.

INSERT PARAPHRASE

This object is achieved in one manner by [the subject matter of Claim 1.]
As a result of the frictionally engaging connection in the manner of a slip coupling, during an injection the container first follows the axial movement of the plunger until the container has reached its proximal end position. The frictionally engaging connection between plunger and container then releases, and allows an expulsion of the preset dose of injection fluid by means of the plunger, which then moves independently of the container.

The stated object is achieved in a different manner by

[the subject matter of Claim 6.] INSERT PARAPHRASE

An injection device of this kind has a simple configuration and operates very reliably and comfortably for the patient.

The stated object is achieved in a different manner by

[the subject matter of Claim 36.] INSERT PARAPHRASE

An injection device of this kind combines high precision with simple operation and compact design.

Other ways of achieving the stated object are evident from

[the subject matters of Claims 44 and 46] The principle of [claim 44]

is highly suitable for injection devices with an automatic injection sequence, and the principle [recited in Claim 46] INSERT PARAPHRASE

is particularly "foolproof" when a used cartridge needs to be replaced with a new one.

The stated object is achieved in another manner by
[the subject matter of Claim 51.] **INSERT PARAPHRASE**

Because the setting member is not in engagement with the dose-setting apparatus when the latter is in its proximal end position, the setting member can there conveniently be reset into its zero position, either manually or preferably automatically, for example by means of a return spring.

In this context, it is particularly advantageous to
[proceed in accordance with Claim 52.] **INSERT PARAPHRASE**

The result is that a dose setting is not possible when the dose-setting apparatus is in the distal end position, but is possible only after leaving that end position. This is important because in this fashion, improper operation due to "playing around" with the setting member can be prevented. This counteracts improper dose setting, and thus constitutes a valuable safety feature.

BRIEF FIGURE DESCRIPTION

Further details and advantageous developments of the invention are evident from the exemplary embodiments described hereinafter and depicted in the drawings - which are in no way to be understood as a limitation of the invention [and from the dependent claims.]
In the drawings:

FIG. 1 is a three-dimensional depiction of an injection device according to the present invention, as an overview depiction;

FIG. 2 is a side view of the injection device of FIG. 1 in which cocking cap 56 is unscrewed and depicted next to the device;

FIG. 2A schematically depicts a development of a scale usable in an injection device according to the present invention;

FIG. 3 is a depiction analogous to FIG. 1, a proximal segment of the barrel being depicted in section;

FIG. 4 is a depiction of the injection device after an injection, the proximal part being depicted in longitudinal section;

FIG. 5 is an exploded, three-dimensional depiction of components of the proximal part of the injection device;

FIG. 6 is an exploded, three-dimensional depiction which shows various components of the middle part of a device according to the present invention;

FIG. 7 is an exploded, three-dimensional depiction analogous to FIG. 6, which also shows parts of a device according to the present invention;

FIG. 8 is a three-dimensional, enlarged, depiction of a preferred form of a plunger that can be used in the present invention;

FIG. 9 is an exploded, three-dimensional depiction of components of the distal part of the injection device, in a depiction analogous to FIGS. 6 and 7 but at a larger scale;

FIG. 10 shows a longitudinal section through a part which forms, inter alia, a clip that serves as trigger for an injection;

FIG. 11 shows a longitudinal section through the setting knob of an injection device according to the present invention;

FIG. 12 is a side view of a component of a setting sleeve that is used for dose setting in an injection device according to the present invention;

FIG. 13 is a greatly enlarged depiction of the parts of a setting sleeve which is used for dose setting in an injection device according to the present invention;

FIG. 14 is a three-dimensional depiction of a front and a rear adapter part, in a depiction enlarged as compared to FIG. 6;

FIG. 15 shows a longitudinal section through various parts that are arranged in the barrel of the injection device, to explain their functional interaction;

FIG. 16 is a depiction of an injection device according to the present invention in which cocking cap 56 is screwed on but the patient has forgotten to insert an injection needle; the device cannot be cocked;

FIG. 17 is an enlarged depiction of detail XVII of FIG. 16;

FIG. 18 is a depiction analogous to FIG. 15, emphasizing various couplings K1 through K10 which, in their functional interaction, contribute to the mode of operation of the injection device according to the present invention;

FIG. 19 shows a longitudinal section through an injection device according to the present invention in its cocked position, i.e. in the position shown in FIGS. 1 and 3;

FIG. 20 shows a section viewed along line XX-XX of FIG. 19;

FIG. 21 shows a section viewed along line XXI-XXI of FIG. 19;

FIG. 22 shows a longitudinal section through an injection device according to the present invention, in its cocked position and after unscrewing the cocking cap; this position corresponds to the position of FIG. 2;

FIG. 23 shows a longitudinal section analogous to FIG. 22, except that an injection dose has been set;

FIG. 24 shows a longitudinal section through an injection device according to the present invention during the first phase of an injection (needle inserted, but before expulsion of injection fluid);

FIG. 25 shows a longitudinal section analogous to FIG. 24 but during the second phase of an injection (expulsion of injection fluid after insertion of the needle);

FIG. 26 shows a longitudinal section depicting the beginning of a cartridge replacement;

FIG. 27 is a depiction which, continuing from FIG. 26, shows a further phase of cartridge replacement;

FIG. 28 is a depiction showing a phase of cartridge replacement subsequent to FIG. 27;

FIG. 29 is an enlarged depiction of detail XXIX of FIG. 28 which shows the latching of plunger 108 in its distal end position;

FIG. 30 is a schematic depiction showing how a used cartridge 52 is removed from cartridge holder 80;

FIG. 31 is a depiction showing how a new cartridge is introduced into cartridge holder 80;

FIG. 32 is a depiction showing how the cartridge holder just loaded (as shown in FIG. 31) is screwed onto the injection device;

FIG. 33 is a depiction showing the phase subsequent to FIG. 32, i.e. the screwing on of the proximal barrel part and the operations occurring in that context;

FIG. 34 is a depiction of a variant in which, as compared to FIG. 1, a plurality of round holes 54A are used as the viewing window;

FIG. 35 is a plan view, viewed in the direction of arrow XXXV, of FIG. 34 but at a scale enlarged relative to FIG. 34;

FIG. 36 is a schematic depiction of splines 220 of setting sleeve 151 and of the interaction between those splines and a latching member 184 during dose setting prior to an injection;

FIG. 37 is a three-dimensional, exploded depiction of parts that play a role in cartridge replacement; and

FIGS. 38 through 40 provide a synoptic depiction to explain the manner of operation of couplings K4 and K5 in various operating states of an injection device according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the description below, the terms "proximal" and "distal" are used in the manner usual in medicine:

"Proximal" = the end facing toward the patient, i.e. in FIG. 3 the lower end of the injection device comprising the needle.

"Distal" = the end remote from the patient, i.e. the upper end in FIGS. 1 and 2.

FIG. 1 depicts, in three-dimensional and schematized form, an injection device 30 according to the present invention. The latter has at its distal end a setting knob 32 that, by rotation in the direction of an arrow 34, makes possible a dose setting if the device is in its position as shown in FIG. 2. (In the position as shown in FIG. 1, dose setting is not activated.) Knob 32 is arranged rotatably in a tubular distal barrel part 36 in which an elongated latch opening 38 is present and on which a resilient clip 40 is mounted. Located in clip 40 is a magnifier 42 for reading off the dose that is set. Clip 40 has a radially inwardly projecting protrusion 44 that serves to trigger an injection and is located opposite elongated latch opening 38.

Adjoining distal barrel part 36 in the proximal direction is an annular part 46 that is immovably joined to barrel part 36. This is followed, in the proximal direction, by a middle barrel part 48. Adjoining this in the proximal direction is a proximal barrel part 50 which receives a cartridge 52 comprising a fluid 53 to be injected (FIG. 4) and is equipped with at least one viewing window 54 through which the fill level of cartridge 52 can be observed.

Advantageously, as shown in FIG. 34, a plurality of small orifices 54A is used as the viewing window. This has the advantage that the patient's fingers cannot reach through window 54 and thereby slow down the motion of cartridge 52 during injection, but that the fill level of cartridge 52 can be very easily observed visually.